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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/940,227 | 08/27/2001 | Sei-Yu Chen | DEX-0230 | 4313 |

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| EXAMINER |
|---|
| BORIN, MICHAEL L |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1631 | |

DATE MAILED: 05/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/940,227 | Chen et al |
| **Examiner** | **Art Unit** |
| Michael Borin | 1631 |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-16 are subject to restriction and/or election requirement.

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## Part III DETAILED ACTION

Claims 1-16 are currently pending.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1(in part), drawn to nucleic acid, classified in class 536, subclass 23.1.

II. Claims 1(in part), 2, drawn to polypeptide encoded by a polynucleotide, classified in class 530, subclass 300.

III. Claims 3-7 (in part), drawn to polynucleotide-based method of cancer diagnostics, classified in class 435, subclass 6.

IV. Claims 3-7 (in part), drawn to peptide-based method of cancer diagnostics, classified in class 435, subclass 7.1.

V. Claim 8 (in part), drawn to polynucleotide-based method of identifying therapeutic agents, classified in class 435, subclass 6.

VI. Claim 8 (in part), drawn to peptide-based method of identifying therapeutic agents, classified in class 435, subclass 7.1

VII. Claims 9,10, drawn to an antibody to a polypeptide, classified in class 530, subclass 388.1.

VIII Claims 9,10, drawn to method of use of an antibody.

IX. Claim13 (in part), drawn to method of cancer treatment using a compound that downregulates expression of polynucleotide of Group I.

X. Claim13 (in part), drawn to method of cancer treatment using a compound that downregulates activity of polypeptide of Group II.

XI. Claims 14,15, drawn to method of inducing immune response using polypeptide of Group II, classified in class 424, subclass 184.1.

XII. Claim 16, drawn to vaccine, classified in class 424, subclass 240.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Group II, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. It is acknowledged that various processing steps may cause a

polypeptide of group II to be directed as to its synthesis by a polynucleotide of Group I, however, the completely separate chemical types of the inventions of Groups I and II supports the undue search burden if both were examined together. Additionally, polypeptides have been most commonly, albeit not always, separately characterized and published in the Biochemical literature, thus significantly adding to the search burden if examined together, as compared to being searched separately. Also, it is pointed out that processing that may connect two groups does not prevent them from being viewed as distinct, because enough processing can result in producing any composition from any other composition if the processing is not so limited to additions, subtractions, enzyme actions, etc.

Inventions I and VII are separate and distinct, as the claims of Inventions I are drawn to polynucleotides, while the claim of group VII is drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. Invention VII would require searching in areas unrelated to polynucleotides, and as such, would require an undue burden on the examiner if not restricted.

Inventions II and VII are separate and distinct as the polypeptides of Invention II are structurally and biochemically different than the antibodies of Invention VII. While the antibodies may bind to the polypeptides of Invention II, the biochemical

activities of each Invention are quite different, requiring differing methods and areas of search, which would impose an undue burden upon the examiner.

Consequently, methods of use of polynucleotides (III, V), polypeptides (IV, VI, XI) and antibodies (VIII) are patentably distinct as they use different products.

Inventions I and III, V are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The inventions are separate and distinct, as the product of Invention I can be used in a materially different processes such as polypeptide production; further, methods III and V are alternative methods of use of product I.

Inventions II and IV,VI, XI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can be used in materially different processes, e.g., in

expression profiles, and methods IV,VI,XI are alternative methods of using the same product.

Methods of us of polynucleotides III, V are related as independent methods which are not disclosed as capable of use together, have different modes of operation, different functions, and different effects. (MPEP 806.04, MPEP 808.01).

Similarly, methods of use of polypeptides of Groups IV, VI, XI are related as independent methods which are not disclosed as capable of use together, have different modes of operation, different functions, and different effects.

Methods of Groups IX and X are unrelated to methods of use of polynucleotides or polypeptides, as they are drawn to use of other products. The methods IX and X are patentably distinct from each other as well, as the former is drawn to method of cancer treatment using a compound that downregulates expression of polynucleotide, while the latter uses for the same purpose a compound that downregulates activity of a polypeptide.

Group XII and VII are drawn to patentably distinct products which require differing characteristics. The vaccine composition requires different host, not required for polypeptide of Group VII, has different pharmaceutical effect, and has separate enablement requirement. In addition, the Groups are differently classified.

***Sequence Election Requirement Applicable to All Groups***

In addition, each Group detailed above reads on a plurality of independent and/or patentably distinct sequences. Each peptide or nucleic acid sequence is independent and/or patentably distinct because they are unrelated compounds, there is no disclosed core structure required for a common utility, and because each of these compounds possess different structure and/or physico-chemical properties, and/or capable of separate manufacture and/or use. **For an elected Group the Applicants must further elect a single amino acid or nucleic acid sequence. This is not an election of species requirement.**

MPEP 803.04 states:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Examination will be restricted only to a Group drawn to elected sequences.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, and the necessity for non-

coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone

are unsuccessful, the examiner's supervisor Mr. Michael Woodward, can be reached at (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

May 16, 2003

mlb